

TDMS No. 20537 - 02
Test Type: 90-DAY
Route: INTRADUCTAL CANNULATION
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Adenoviral Vector (AdhAQP1)
CAS Number: ADNIRVECAQP

Date Report Requested: 09/10/2009
Time Report Requested: 11:36:30
First Dose M/F: NA / 07/25/05
Lab: MBA

F1_R2_9Wk_SSAC

C Number: C20537
Lock Date: 11/19/2007
Cage Range: ALL
Date Range: ALL
Reasons For Removal: 25017 SSAC
Removal Date Range: ALL
Treatment Groups: Include 002 VEHCONTRCOHRTB Include 004 VEHCONTRCOHRTD Include 009 2-8ADHAQP1COHTD
Include 014 8-9ADHAQP1COHTD Include 019 2-11ADHAQP1COHTD
Study Gender: Female
TDMSE Version: 2.1.0

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
LAST REMOVAL AT 9 WEEKS**

Females			
DOSE	VEHCONTRCOHRTD	2-11ADHAQP1COHTD	8-9ADHAQP1COHTD
Heart Cardiomyopathy			
LESION RATES			
OVERALL (a)	3/5 (60%)	3/10 (30%)	1/5 (20%)
POLY-3 RATE (b)	3/5.00	3/10.00	1/5.00
POLY-3 PERCENT (g)	60%	30%	20%
INT SACRIFICE 1	3/5 (60%)	3/10 (30%)	1/5 (20%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	57 (I)	57 (I)	57 (I)
STATISTICAL TESTS			
POLY 3	P=0.272N	P=0.293N	P=0.264N
POLY 1.5	P=0.272N	P=0.293N	P=0.264N
POLY 6	P=0.272N	P=0.293N	P=0.264N
COCH-ARM / FISHERS	P=0.266N	P=0.287N	P=0.262N
MAX-ISO-POLY-3	P=0.141N	P=0.174N	P=0.103N

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N) LAST REMOVAL AT 9 WEEKS

Females				
DOSE	VEHCONTRCOHRTD	2-11ADHAQP1COHTD	8-9ADHAQP1COHTD	
Liver Inflammation				
LESION RATES				
OVERALL (a)	3/5 (60%)	4/10 (40%)	2/5 (40%)	
POLY-3 RATE (b)	3/5.00	4/10.00	2/5.00	
POLY-3 PERCENT (g)	60%	40%	40%	
INT SACRIFICE 1	3/5 (60%)	4/10 (40%)	2/5 (40%)	
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	
FIRST INCIDENCE	57 (I)	57 (I)	57 (I)	
STATISTICAL TESTS				
POLY 3	P=0.500N	P=0.431N	P=0.500N	
POLY 1.5	P=0.500N	P=0.431N	P=0.500N	
POLY 6	P=0.500N	P=0.431N	P=0.500N	
COCH-ARM / FISHERS	P=0.500N	P=0.427N	P=0.500N	
MAX-ISO-POLY-3	P=0.386N	P=0.274N	P=0.282N	

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LAST REMOVAL AT 9 WEEKS**

Females			
DOSE	VEHCONTRCOHRTD	2-11ADHAQP1COHTD	8-9ADHAQP1COHTD
Salivary Glands: Submandibular Gland, Right Inflammation			
LESION RATES			
OVERALL (a)	0/5 (0%)	3/9 (33%)	0/4 (0%)
POLY-3 RATE (b)	0/5.00	3/9.00	0/4.00
POLY-3 PERCENT (g)	0%	33.3%	0%
INT SACRIFICE 1	0/5 (0%	3/9 (33%	0/4 (0%
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	57 (l)	---
STATISTICAL TESTS			
POLY 3	P=0.559N	P=0.217	(e)
POLY 1.5	P=0.559N	P=0.217	(e)
POLY 6	P=0.559N	P=0.217	(e)
COCH-ARM / FISHERS	P=0.557N	P=0.231	(e)
MAX-ISO-POLY-3	P=0.263	P=0.098	(e)

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Females			
DOSE	VEHCONTRCOHRTD	2-11ADHAQP1COHTD	8-9ADHAQP1COHTD
Salivary Glands: Submandibular Gland, Right Regeneration			
LESION RATES			
OVERALL (a)	5/5 (100%)	9/9 (100%)	4/4 (100%)
POLY-3 RATE (b)	5/5.00	9/9.00	4/4.00
POLY-3 PERCENT (g)	100%	100%	100%
INT SACRIFICE 1	5/5 (100%	9/9 (100%	4/4 (100%
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	57 (I)	57 (I)	57 (I)
STATISTICAL TESTS			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)

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LEGEND

- (a) Number of tumor-bearing animals/number of animals examined at site.
 - (b) Number of tumor-bearing animals/Poly-3 number
 - (d) Observed incidence at terminal kill.
 - (e) Value of Statistic cannot be computed.
 - (f) Beneath the control incidence are the P-values associated with the trend test. Beneath the dosed group incidence are the P-values corresponding to pairwise comparisons between the controls and that dosed group.
 - (g) Poly-3 adjusted lifetime tumor incidence.
 - (I) Interim sacrifice
 - (T) Terminal sacrifice
 - # Tumor rates based on numbers of animals necropsied.
 - * To the right of any statistical result, indicates significance at ($P \leq 0.05$).
 - ** To the right of any statistical result, indicates significance at ($P \leq 0.01$).
 - N Indicates a negative trend for all tests
- The Cochran-Armitage and Fishers exact tests compare directly the overall incidence rates.

*** END OF REPORT ***